REMARKS

Claims 1 to 3, 58, and 59 are pending in the application.

Claims 2 and 58 and the specification are amended.

Claim 1 is cancelled without prejudice to filing a divisional application.

Claims 2, 3, 58, and 59 would be all of the claims pending in the present application if this amendment is entered.

Specification

Applicants have corrected the typographical error in the chemical name of Example 40 that was identified in the Office Action and have searched for but did not find other typographical errors in the specification. The title has been amended to the title suggested in the Office Action.

Claim Rejections – 35 U.S.C. § 112

In the Office Action, claims 1-3, 58, and 59 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. In the Office Action, it was alleged that it was not stated to whom the gamma-amino-butyric acid (GABA) analog is to be administered. Applicants traverse the rejection in view of the cancellation of claim 1 and the amendments of claims 2 and 58 inserting the phrase "to the mammal." The inserted phrase explicitly states what was implicitly present before.

Claim Rejections – 35 U.S.C. § 112

In the Office Action, claim 1 is rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of treating certain forms of cartilage damage in a mammal by administering a therapeutically effective dose of a GABA analog of Formula I, or a pharmaceutically acceptable salt thereof, allegedly does not reasonably provide enablement for all compounds that could be described by the phrase "GABA analog having the characteristic of being an inhibitor of cartilage damage." Applicants traverse the rejection because they believe claim 1 is enabled. To further prosecution, however, claim 1 is canceled, rendering the rejection of claim 1 moot.

Claim Rejections – 35 U.S.C. § 103

In the Office Action, claims 1-3 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lu et al. in view of Minor and the Merck Manual.[1] It was stated in the Office Action that Lu et al. teach the use of gabapentin for the relief of nociceptive pain, including arthritic pain, wherein the relief did not relate to improving inflammation. It was acknowledged in the Office Action that Lu et al. do not teach the use of gabapentin for treating noninflammatory cartilage damage. It was stated in the Office Action that Minor suggests exercise for osteoarthritis (OA) patients and that the Merck Manual mentions that "Exercise (. . .) maintains healthy cartilage," and also that "[i]mmobilization can accelerate and worsen the clinical course [of OA]. Arrest and occasionally reversal of hip and knee OA can occur using well-planned exercise as therapy" (page 451). It was argued in the Office Action that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teaching of Lu et al. by administering gabapentin to OA patients who suffered from severe chronic pain that precluded them from engaging in a healthy level of physical activity. It was further argued in the Office Action that the skilled artisan would have reasonably expected success in view of the well-established history of treating OA with pain relieving medications.

While Applicants disagree with the rejection of claim 1, claim 1 is canceled to advance prosecution, rendering the rejection of it moot. Applicants traverse the rejection of claims 2 and 3 because:

- there was no reasonable expectation of success for using gabapentin to treat noninflammatory cartilage damage at the time the present application was filed; and, independently,
- the present invention omits a required element of Lu et al. in view of Minor and the Merck Manual, and omission of an element with retention of the element's function is an indication of unobviousness.

NO REASONABLE EXPECTATION OF SUCCESS

Minor and the Merck Manual mention exercise therapy for OA, and Lu et al. mention gabapentin for treating nociceptive arthritic pain. But Applicants believe that Lu

[1] Lu et al., J. Pharm. & Exper. Ther., 1999, vol. 290(1): pages 214-219; Minor, Arthritis & Rheumatism, 1996, vol. 9(2): pages 79-81; and the Merck Manual of Diagnosis and Therapy, 7th edition, pages 449-451 (1999).

et al. in view of Minor and the Merck Manual do not teach or suggest any pain relieving medication for treating noninflammatory cartilage damage.

Noninflammatory cartilage damage is a "disorder of hyaline cartilage and subchondral bone characterized by hypertrophy of tissues in and around the involved joints, which may or may not be accompanied by deterioration of hyaline cartilage surface" (page 44, lines 1-4 of the specification). Noninflammatory cartilage damage is a pathological effect distinct from arthritic pain.

Lu et al. provide no evidence (e.g., experimental data or literature references) suggesting that the use of gabapentin or, for that matter, any other compound of present Formula I for treating any type of cartilage damage would be successful. Minor and the Merck Manual do not cure the deficiency of Lu et al. because they also fail to provide any such evidence.

Applicants believe that such evidence is required for a proper obviousness rejection.[2] In a case on point, the Federal Circuit in *In re O'Farrell*[3] characterized prior art references, known as the Polisky reference and the Bahl reference, as follows:

> "We agree with the board that appellants' claimed invention would have been obvious in light of the Polisky reference alone or in combination with Bahl within the meaning of §103. Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful. "(7 USPQ2d 1680 , first column, last paragraph; emphasis added).
>
> "The information in the Polisky reference, when combined with the Bahl reference provided such a reasonable expectation of success." (7 USPQ2d 1681, first column, last complete paragraph)

But Lu et al. in view of Minor and the Merck Manual do not provide evidence suggesting that the use of gabapentin or any other compound of present Formula I for treating noninflammatory cartilage damage would be successful. Thus, Applicants believe that claims 2 and 3 are nonobvious because there was no reasonable expectation of

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[2] Manual of Patent Examining Procedure, 8th ed. Incorporating revision no. 2, 2004, §2145 (X)(B), page 2100-161

[3] *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); see also footnote 2.

success for using gabapentin to treat noninflammatory cartilage damage at the time the present application was filed.

OMISSION OF AN ELEMENT WITH RETENTION OF THE ELEMENT'S FUNCTION IS AN INDICATION OF UNOBVIOUSNESS

Lu et al. relates to gabapentin for relief of arthritic pain and it was acknowledged in the Office Action that Lu et al. do not teach the use of gabapentin for treating noninflammatory cartilage damage. Minor relates to arthritis and exercise and the Merck Manual mentions well-panned exercise therapy in connection with treating OA, but Minor and the Merck Manual do not teach or suggest using gabapentin for treating noninflammatory cartilage damage. Accordingly, Applicants believe that it was argued in the Office Action that Lu et al. in view of Minor and the Merck Manual suggest a combination therapy of using gabapentin for arthritic pain relief and well-planned exercise therapy for treating cartilage damage of OA.

In contrast the present invention omits the element of well-planned exercise and retains the element's function of treating cartilage damage. Omission of an element with retention of the element's function is an indication of unobviousness.[4] Thus, Applicants also believe that claims 2 and 3 are nonobvious because the invention of claims 2 and 3 omits the exercise element of Lu et al. in view of Minor and the Merck Manual and retains the element's function of treating cartilage damage, which is noninflammatory cartilage damage in the invention of claims 2 and 3.

Accordingly in view of the above remarks, Applicants believe that claims 2 and 3 are not obvious over Lu et al. in view of Minor and the Merck Manual, and are patentable under 35 U.S.C. § 103(a).

Claim Rejections - 35 U.S.C. § 101 Double Patenting

Claims 58 and 59 are rejected under 35 U.S.C. § 101 as allegedly claiming the same invention as that of claims 4 or 5, respectively, of U.S. Patent No. 6,620,829.

Applicants traverse the rejection because claims 4 and 5 of U.S. 6,620,829 are not the same invention as what is being claimed in instant claims 58 and 59. Claims 4 and 5 of U.S. 6,620,829 relate to compounds, whereas instant claims 58 and 59 relate to

[4] Manual of Patent Examining Procedure, 8th ed. Incorporating revision no. 2, 2004, §2144.04 (II)(B), page 2100-139

pharmaceutical compositions comprising the compounds and a pharmaceutically acceptable carrier, diluent, or excipient. Thus the instant claims are not co-extensive in scope with the claims of U.S. 6,620,829. Accordingly, Applicants believe that the rejection of claims 58 and 59 for same invention double patenting is overcome and that claims 58 and 59 are patentable under 35 U.S.C. § 101 over US 6,620,829.

Conclusion

In view of the above amendments and remarks, Applicants believe that the rejections are overcome. Applicants believe that claims 2, 3, 58, and 59 are patentable and respectfully request reconsideration and allowance thereof.

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Respectfully submitted,

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